

REMARKS

The following remarks are offered in complete response to the Office Action dated May 8, 2008. In light of these remarks and the foregoing amendments, reexamination and reconsideration are respectfully requested.

Claims 1, 2, 4-15, 17, 18 and 20 are pending in this application.

Claim 1 has been amended to change the identify of the step of coacervating the at least one solubilized plant protein and the polyelectrolyte having an opposite charge from being designated as step (e) to being designated as step (d). This amendment was made because there was no step designated as step (d) in the previous version of the claims. No new matter has been added in making this amendment.

Claim 1 was objected to because Claim 1 had steps (a), (b), (c) and (e), but did not have a step (d).

Claim 1 has been amended to change the designation of step (e) to step (d).

Applicants request the withdrawal of this objection.

Claims 1, 2, 4, 7-13, 15, 17, 18 and 20 have been rejected under 35 U.S.C. §103(a) as unpatentable over Yajima et al. ("Yajima") (JP 05-309261). in view of Gillberg-Laforce et al. ("Gillberg-Laforce") (U.S. Patent No. 5,618,622) and Ezpeleta et a. ("Ezpeleta") (International Journal of Pharmaceuticals, 131 (1996) 191-200).

Applicants respectfully submit that these claims are not obvious over Yajima et al. in view of Gillberg-Laforce et al. and Ezpeleta et al. and that all of the claims as amended are allowable.

To establish a *prima facie* case of obviousness, three basic criteria must be met. (MPEP 2143) First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Yajima discloses a method producing microcapsules by complex coacervation of a polycationic material (wheat gluten extract) and a polyanionic material using ethanol/water solutions containing various organic acids to extract the protein from gluten at high temperatures (70°C in the Example). Yajima teaches that after separating the solid particles in the extract, the supernatant (an ethanol/water solution) is used in making the microcapsules by coacervation. Yajima does not teach the use of cationic polyelectrolytes, or the use of glutaraldehyde as a crosslinking agent for hardening the microcapsules.

Gillberg-Laforce disclose surface modified fibrous materials that are used as a filtration medium. Gillberg-Laforce disclose the fibers are coated with a polyelectrolyte. Gillberg-Laforce define the term "polyelectrolyte" as:

The term "polyelectrolyte" is used herein to mean a polymer having a high molecular weight and producing large chain-type ions in solutions. The term is intended to cover complexes of a polyelectrolyte with oppositely charged molecules, e.g. monomers or low molecular weight polymers, such that the net charge of the complex is of the same type as the polyelectrolyte per se.

They also teach that in their invention, the term does not include proteins, and that the use of proteins may be undesirable in their invention. (See col. 4, lines 43-50). Gillberg-Laforce does not disclose making nanoparticles by any method, and especially does not disclose making nanoparticles by coacervating a plant protein with a polyelectrolyte. Gillberg-Laforce does not disclose solubilizing a plant protein in an aqueous medium. In fact Gillberg-Laforce is silent on all aspects of the Applicant's invention except for the element of a polyelectrolyte.

Ezpeleta disclose gliadin nanoparticles made by dissolving gliadin in an organic solvent/water phase, pouring this solution into a saline solution containing Synperonic PE/F 68 as a stabilizer and then removing the organic solvent under a vacuum to produce the nanoparticles. The effects of a variety of organic solvent/water mixtures on characteristics of the nanoparticles formed was evaluated. The ratio of organic solvent to water varied from approximately 4:1 to 1:1. Gliadin is a group of proteins extracted from gluten with 70% ethanol. Gliadin can be characterized into being in one of four fractions based on their molecular mass. All fractions have remarkably low solubility in water except at extreme pH. Ezpeleta does not disclose making nanoparticles without the presence an organic solvent in the water. In fact Ezpeleta requires removal of the organic solvent from the solution in order to form the nanoparticles and uses desolvation to form the nanoparticles. Ezpeleta does not use the process of coacervation, which is the process used in the Applicant's invention.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

combine reference teachings. There is no suggestion or motivation in Yajima, Gillberg-Laforce or Ezpeleta to modify or combine the reference teachings to obtain the method of the applicants' invention. None of these references provide any suggestion or motivation to solubilize at least one plant protein in an aqueous medium at a pH that is between 2 and 7 to obtain a solution comprising at least one solubilized plant protein. Yajima teaches away from using an aqueous solution by teaching that the prior art to their invention used high amounts (50-70%) ethanol in water, and their improvement was to use 1-20% ethanol in water, and preferably 5-10% ethanol in water. One of ordinary skill in the art, upon reading Yajima would interpret that the preferable range of 5-10% ethanol indicates that 1-5% ethanol in water is less effective than 5-10% ethanol in water and therefore some ethanol is needed for their process to be effective. This would teach away from using an aqueous solution. Ezpeleta requires the use of an organic solvent/water mixture in order for the process of desolvation, which was used to form the nanoparticles, to work. Ezpeleta also teaches away from the use of an aqueous solution by investigating a variety of organic solvent/water solutions but not trying or reporting the use of only an aqueous solution. Gillberg-Laforce does not use plant proteins and provides no information relevant to the claimed process. Therefore, there is no suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to obtain the invention of the instant application.

To establish a *prima facie* case of obviousness, there must be a reasonable expectation of success. There is no reasonable expectation of success based on the teachings in Yajima, Gillberg-Laforce or Ezpeleta to obtain a process that

requires the step of (a) solubilizing at least one plant protein in an aqueous medium at a pH that is between 2 and 7 to obtain a solution comprising at least one solubilized plant protein. Both Yajima and Ezpeleta teach away from using an aqueous medium by teaching using organic solvents/water mixtures. This is especially true when Ezpeleta studies the effects of a variety of organic solvent/water mixtures, but did not teach or suggest using only an aqueous solution as the solvent. Therefore Ezpeleta and Yajima teach away from using an aqueous solution to dissolve the plant protein. Gillberg-Laforce does not disclose solubilizing plant protein in any solvent. There cannot be a reasonable expectation of success in obtaining the Applicants' invention when the cited prior art provides teachings that require an organic solvent/water mixture and teach against use of only an aqueous solution. Therefore there is no reasonable expectation of success in producing the applicants' invention based on the teachings in the cited prior art.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Neither Yajima, Gillberg-Laforce nor Ezpeleta teach or suggest solubilizing the plant protein in an aqueous medium. Both Yajima and Ezpeleta require solubilizing the protein in an organic solvent/water medium, while Gillberg-Laforce does not mention solubilizing a protein. Therefore, the prior art references, either alone or combined do not teach or suggest all the claim limitations.

Applicants respectfully submit that the claims are not obvious over Yajima et al. in view of Gillberg-Laforce et al. and Ezpeleta et al. and the rejection should be withdrawn.

Claims 5 and 6 have been rejected under 35 U.S.C. §103(a) as unpatentable over Yajima et al. ("Yajima") (JP 05-309261), in view of Gillberg-Laforce et al. ("Gillberg-Laforce") (U.S. Patent No. 5,618,622), Ezpeleta et al. ("Ezpeleta") (International Journal of Pharmaceuticals, 131 (1996) 191-200) and Kangas et al. ("Kengas") (US 3,843,585).

Applicants respectfully submit that these claims are not obvious over Yajima et al. in view of Gillberg-Laforce et al., Ezpeleta et al. and Kengas et al. and that both of these claims allowable.

The teachings of Yajima, Gillberg-Laforce and Ezpeleta are provided above.

The Office Action describes the teachings of Kengas.

Claims 5 and 6 depend from claim 2, which depends from claim 1. It was shown above that claims 1, 2, 4, 7-13, 15, 17, 18 and 20 are not obvious over Yajima et al. in view of Gillberg-Laforce et al. and Ezpeleta et al. Kengas does not overcome the deficiencies of Yajima, Gillberg-Laforce and Ezpeleta and therefore claims 5 and 6 are not obvious over the cited prior art.

Applicants respectfully submit that the claims are not obvious over Yajima et al. in view of Gillberg-Laforce et al. and Ezpeleta et al. and Kengas and the rejection should be withdrawn.

Applicants note that the combination of references as cited in the Office Action uses various selected features from different references without considering the teachings of each reference to determine the relevance and motivation to use the reference. While Ezpeleta teaches forming microparticles by the process of desolvation, there is nothing in the Office Action that explains why one of ordinary

skill in the art would take the specific features recited in the Office Action that are used in desolvation and use them in a process that requires coacervation, where these two processes operate by totally different mechanisms. Similarly, Gillberg-Laforce is related to surface modified fibrous materials that are used as a filtration medium which is not in any way related to producing nanoparticles. The Office Action provides no rationale for one of ordinary skill in the art to selectively choose using chitosan and sodium carboxymethylcellulose to produce nanoparticles from a reference on surface modified fibrous materials that are used as a filtration medium. Applicants believe this represents a classic case of "hindsight reconstruction."

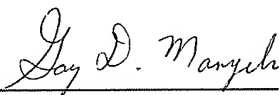
In view of the foregoing amendments and remarks, applicants respectfully request reconsideration and withdrawal of all outstanding rejections. Applicants submit that the claims are now in condition for allowance, and respectfully request formal notification to that effect. If, however, the Examiner perceives any impediments to such a notice of allowability, whether substantive or formal, the Examiner is encouraged to call Applicants' attorney at the number provided below. Such informal communication will expedite examination and disposition of this case.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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